DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: CAMPTOSAR®
Docket No. 96E-0379

Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, D.C. 20231

Dear Mr. Kunin:

This is in regard to the patent term extension application for U.S. Patent No. 4,604,463 filed by Kabushiki Kaisha Yakult Honsha under 35 U.S.C. § 156. The patent claims the human drug product CAMPTOSAR® (irinotecan hydrochloride), New Drug Application (NDA) 20-571.

In the January 28, 1997 issue of the Federal Register (62 Fed. Reg. 4066), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before July 28, 1997, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely,

Ronald L. Wilson

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Leonard R. Svensson
Birch, Stewart, Kolasch, Birch, LLP
P.O. Box 747
Falls Church, VA 22040-0747

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